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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,899	05/31/2001	Mark E. Wilson	834460-68474	1013

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EXAMINER
JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N . 09/870,899	Applicant(s) WILSON ET AL.	
	Examiner Shaojia A. Jiang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20, 25, 41(in part), 60-62, 65, 67, 69 (in part), and 70-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20, 25, 41(in part), 60-62, 65, 67, 69 (in part), and 70-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9 .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on October 28, 2002 in Paper No. 7 wherein claims 21-22, 24, 26-40, 41 (in part), 42-59, 63-64, 66, and 68 are cancelled and claims 1-20, 25, 41(in part), 60-62, 65, 67, 69 (in part), and 70 have been amended and claims 71-72 are newly submitted. Currently, claims 1-20, 25, 41(in part), 60-62, 65, 67, 69, and 70-72 are pending in this application.

It is noted that 41 contains the subject matter, i.e., administering to a male swine, drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action, i.e., amend the claim (37 CFR 1.144) See MPEP § 821.01.

The declarations of Dr. Stephen K. Webel, Dr. Douglas M. Webel (inventor), and Dr. Donald E. Orr (inventor) submitted October 28, 2002 in Paper No. 8 under 37 CFR 1.132, are acknowledged and will be further discussed below.

Applicant's amendment and remarks filed on October 28, 2002 in Paper No. 7 with respect to the rejection of claims 1-20, 25, 41(in part), 60-62, 65, 67, 69 (in part), and 70 made under 35 U.S.C. 112 second paragraph for the use of the indefinite expressions, i.e., "the reproductive performance" in claims 1, 41 (in part) and 69, and The expression "biologically effective amount" in claims 1, 20, 25, 41 (in part), 61-62, 67, 69 (in part) and 70, of record stated in the Office Action dated April 23, 2002 have been fully considered and found persuasive to remove the rejection since the

expression "the reproductive performance" is seen to be clearly defined in the specification, and the expression "biologically effective amount" has been deleted from the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-20, 25, 41(in part), 60-62, 65, 67, 69 (in part), and 70-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stitt (5,110,592, PTO-1449 submitted February 15, 2002) in view of Applicant's admission regarding the prior art in the specification of pages 1-3 and Boudreaux et al. (HY, PTO-1449 submitted February 15, 2002) for reasons of record stated in the Office Action dated April 23, 2002.

The changed limitation from "omega-3 fatty acids selected from the group consisting of eicosopentenoic acid, docosohexanoic acid, and docosapentaenoic acid" to "C20 and C22 omega-3 fatty acids or esters thereof " in amended claims 65, 67, 69-70 and new claims 71-72 does not render the claimed methods nonobvious over the prior art as discussion below.

Stitt discloses that omega-3 fatty acids such as alpha-linolenic acid, eicosopentenoic acid, and docosohexanoic acid in an edible composition comprising

flaxseed to be administered daily is useful in a method for increasing the number of live births to a female animal such as a female swine. Stitt teaches that flaxseed is known to contain omega-3 fatty acids such as alpha-linolenic acid, eicosopentenoic acid, and docosohexanoic acid. See abstract, col.1 line 35-68, col.4 lines 13-17, col.5 line 58 to col.6 line 15, and claims 1-61.

Stitt does not expressly disclose that the sources of same omega-3 fatty acids as the instant claims are not derived from fish oils. Stitt does also not expressly disclose the employment of these omega-3 fatty acids in combination with omega-6 fatty acids in a composition and a method for increasing the reproductive performance such as increasing the number of live births to a female swine. Stitt does not expressly disclose the ratio of omega-6 fatty acids to omega-3 fatty acids herein in the composition to be administered to a female swine.

Applicant's admission regarding the prior art in the specification of pages 1-3 teaches the following: the instant omega-3 fatty acids such as eicosopentenoic acid, and docosohexanoic acid and docosapentaenoic acid are well known to be derived from fish oils and marine algae (see page 2 lines 13-14); Omega-6 fatty acids are known to increase the number of live births in animals (see page 2 lines 24-25); Salmon oil is known to be used in animal food (see page 2 lines 26-27); Omega-3 fatty acids in particular are known to be useful to increase female animal fertility (see page 2 lines 29-30); Salmon oil is known to contain both omega-3 fatty acids and omega-6 fatty acids (see page 3 lines 1-3).

Boudreaux et al. discloses that the range of the ratio of omega-6 fatty acids to omega-3 fatty acids herein in the composition to be administered to animals is within the instant claim. See abstract and page 236 3rd paragraph of left column.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ omega-3 fatty acids herein which are derived from fish oil in the claimed method for increasing the reproductive performance, to employ these omega-3 fatty acids in combination with omega-6 fatty acids in a composition and the claimed method herein, to optimize the ratio of omega-6 fatty acids to omega-3 fatty acids herein in the composition to be administered to a female swine.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ omega-3 fatty acids herein which are derived from fish oil in the claimed method for increasing the reproductive performance, to employ these omega-3 fatty acids in combination with omega-6 fatty acids in a composition and the claimed method herein, because omega-3 fatty acids herein are known to be useful in an edible composition to be administered daily and in a method for increasing the number of live births to a female swine based on the prior art. Omega-3 fatty acids in particular are known to be useful to increase female animal fertility. Omega-6 fatty acids are also known to increase the number of live births in animals. Moreover, the instant omega-3 fatty acids such as eicosopentenoic acid, and docosohexanoic acid and docosapentaenoic acid are well known to be derived from fish oils and marine algae. Salmon oil is known to contain both omega-3 fatty acids and omega-6 fatty acids. Therefore, one of ordinary skill in the art would have reasonably employed any fish oils

and marine algae such as salmon oil as sources of omega-3 fatty acids and omega-6 fatty acids, so long as these fish oils contain omega-3 fatty acids and omega-6 fatty acids. Applicant is further requested to note that the sources of omega-3 fatty acids and/or omega-6 fatty acids are not considered a limitation to a composition comprising omega-3 fatty acids and/or omega-6 fatty acids. Therefore, one of ordinary skill in the art would have reasonably expected that combining omega-3 fatty acids and omega-6 fatty acids known useful for the same purpose i.e., increase female animal fertility, in a composition to be administered would improve the therapeutic effect for increasing the reproductive performance of a female swine such as increasing the number of live births of a female swine.

Since all active composition components herein are known to useful to increase the number of live births in animals, it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Additionally, one of ordinary skill in the art would have been motivated to optimize the ratio of omega-6 fatty acids to omega-3 fatty acids herein in the composition to be administered to a female swine because the range of the ratio of omega-6 fatty acids to omega-3 fatty acids herein in the composition to be administered to animals are known in the art and the optimization of amounts of active agents to be administered is considered well within the skill of artisan.

Applicant's remarks filed on October 28, 2002 in Paper No. 7 and The declarations of Dr. Stephen K. Webel, Dr. Douglas M. Webel (inventor), and Dr. Donald E. Orr (inventor) submitted October 28, 2002 in Paper No. 8 under 37 CFR 1.132, with respect to this rejection of claims 1-20, 23, 25, 41(in part), 60-62, 65, 67, 69 (in part), and 70 made under 35 U.S.C. 103(a) in the previous Office Action dated April 23, 2002 have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

First, regarding the changed limitation from "omega-3 fatty acids selected from the group consisting of eicosopentenoic acid, docosohexanoic acid, and docosapentaenoic acid" to "C20 and C22 omega-3 fatty acids or esters thereof " in amended claims 65, 67, 69-70 and new claims 71-72, according to the cited prior art and Applicant's admission regarding the prior art in the specification of pages 1-3 teaches the following: omega-3 fatty acids broadly in a edible composition to be administered daily is useful in a method for increasing the number of live births to a female animal such as a female swine based on Stitt; Omega-3 fatty acids in particular are known to be useful to increase female animal fertility (see the instant specification page 2 lines 29-30); the instant omega-3 fatty acids including C20 and C22 omega-3 fatty acids are well known to be derived from fish oils such as Salmon oil (see page 2 lines 13-14 and page 15). Therefore, one of ordinary skill in the art would have reasonably employed any fish oils and marine algae such as salmon oil as sources of omega-3 fatty acids and omega-6 fatty acids in the instant claimed methods, so long as they contain omega-3 fatty acids and omega-6 fatty acids.

Additionally, Applicants arguments and the declarations of Dr. Stephen K. Webel, Dr. Douglas M. Webel and Exhibit E, regarding that "flaxseed lacks C20 and C22 omega-3 fatty acids" have been fully considered but are not deemed persuasive. There is no factual data in the declarations in support of Applicant's statement that "flaxseed lacks C20 and C22 omega-3 fatty acids".

Moreover, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of prior art. In re Keller, 642 F.2d 413, 208 SPQ 871 (CCPA 1981); In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). See MPEP 2145. In the instant case, as discussed above, omega-3 fatty acids in particular are known to be useful to increase female animal fertility and the composition containing omega-3 fatty acids broadly are known to be useful in a method for increasing the number of live births to a female animal such as a female swine according to Stitt. Therefore, one of ordinary skill in the art would clearly expect that C20 and C22 omega-3 fatty acids would have same or similar therapeutic usefulness as all other omega-3 fatty acids in the claimed methods herein, absent evidence to the contrary.

The declarations of Dr. Stephen K. Webel, Dr. Douglas M. Webel with respect to the set forth 103(a) rejection have been fully considered but are ineffective to overcome this rejection since the declarations merely present statements or conclusions, but fails to set forth any factual evidences in support of their statements or conclusions in the

declarations. Therefore, the declarations are insufficient to rebut the prima facie case herein.

Applicant's remarks filed on October 28, 2002 in Paper No. 7 and the declaration of Dr. Donal E. Orr (inventor) submitted October 28, 2002 in Paper No. 8 under 37 CFR 1.132, with respect to that Applicants' claimed invention has met with great commercial success, have been fully considered but are not deemed persuasive since the declaration merely shows the value of sales (US dollars) per the number pounds sold in the monthly sales for 2002 for Applicant's product Fertilium™, absent a full market information and comparison, for example, with competitors and prices. Thus, the declaration of Dr. Donal E. Orr is insufficient to establish the fact that Applicants' claimed invention has met with great commercial success. Therefore, the declaration of Dr. Donal E. Orr is ineffective to overcome the set forth 103(a) rejection.

Applicant's data shown in the Examples 1-5 of the specification at pages 15-26 herein have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention over the prior art but are not deemed persuasive for the reasons below. Examples 1-5 provide no clear and convincing evidence of nonobviousness or unexpected results over the cited prior art since there is no comparison to the same present. Therefore, the evidence presented in specification herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
January 15, 2003

SREENI PADMANABHAN
PRIMARY EXAMINER

1/27/03